HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

MS2000

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

February 21, 2001

VIA FEDERAL EXPRESS

Ms. Rita D. Walling, President
United American Medical Company, Inc.
8120 Beersheba Highway
McMinnville, TN 37110-3934

Warning Letter No. 01-NSV-13

Dear Ms. Walling:

During an inspection of your firm located in McMinnville, Tennessee, on January 25-29, 2001, our investigator determined that your firm is the specification developer, assembler, and distributor of devices used during small bone orthopedic procedures. Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body.

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacture, packing, storage or installation are not in conformance with the current good manufacturing practices (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) for Medical Devices regulations were superseded on June 1, 1997, by the Quality System Regulation.

The inspection revealed deviations from 21 CFR 820 including failure to conduct internal audits, inadequately trained personnel to perform assigned duties, no change control procedures, no verification and acceptance criteria for incoming and packaged products, failure to calibrate testing equipment, incomplete Device Master Records and Device History Records, and inadequate Medical Device Reporting procedures.

The inspection also revealed that labels for some of the products failed to bear the address of your facility as required by 21 CFR 801.1(d).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's operation and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission for devices to which GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

CED:JEH:man

Enclosures:
FDA 483
21 CFR 801.1 – 801.63
21 CFR 820

cc: Sylvia J. Southard
Chief Operations Officer
United American Medical Co. Inc.
8120 Beersheba Hwy.
McMinnville, TN 37110